JUN 6 - 2005 K050776

Exhibit E 510(k) SUMMARY - Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator System and Accessories

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification**

Submitter's Name:	MISONIX INCORPORATED
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	516-694-9555
Contact Person:	Ronald R. Manna
Date Prepared:	February 5, 2005

2. **Name of Device**

Proprietary Name:	Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator System and Accessories
Common/Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Classification Name:	Instrument, Ultrasonic Surgical

3. **Predicate Device Information**

Predicate Devices	CUSA NS-100 Ultrasonic Surgical Aspirator System K801623 Alliger Ultrasonic Surgical System AUSS-5 K012028

4. **Device Description**

The AUSS-6 Ultrasonic Surgical System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. An irrigation unit is provided to introduce irrigation solution to the operative site. An aspirator system removes fragmented material and waste liquids from the area. Accessories include probe tips, wrenches, sterile and non sterile tube sets and sterile Surgical Procedure bags.

5.	**Intended Use:**	The AUSS-6 Ultrasonic Surgical Aspiration System and Accessories are indicated for the fragmentation and aspiration of soft and hard (i.e. bone) tissues in various General and Specialty surgery applications. It is also indicated for use in the debridement of wounds (such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers), soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.
6.	**Comparison to Predicate Device**	AUSS-6 Ultrasonic Surgical Aspirator System and Accessories are similar in design, material and operating parameters to the Misonix Inc. AUSS-5 Ultrasonic Surgical Aspirator, the CUSA NS-100 Ultrasonic Surgical Aspirator.

7. **Safety and Performance Data**

The Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator System and Accessories have been designed and tested to pass the following Voluntary Standards:

UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-2:2001 Electromagnetic Compatibility
FCC Part 18 EMC Requirements

7.	**Software Validation**	This device does not contain software.
8.	**Sterilization Validations**	Validation statements are contained in Exhibit J.

9. **Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Output Frequency Measurements
Output Power Measurements (No Load to Maximum Load)
Tip Displacement Measurements
Irrigation Flowrate Measurements
Life Tests
Vacuum Flowrate and Pressure Measurements
Input Power Measurements
EMI Tests
Dielectric Tests on Mains Circuits
Patient Current Leakage and Patient Sink Current Measurements
Power Line Ground Leakage Measurements
Dielectric Tests on Patient Circuits

9. **Discussions of Clinical Tests Performed**

The FDA has cleared all indications for use in the predicates since the early 1980's, with the exception of the express indication of Wound Debridement. Ultrasonic Surgical Aspirators have been employed for use in soft and hard tissue ablation for the past 30 years and are well documented in the public domain. Therefore, no clinicals were conducted in anticipation of this submission for those indications.

The use of an Ultrasonic Surgical System for debriding and cleansing of burns, ulcers or septic wounds has been investigated for decades. Several papers have discussed the use of the product in such applications and tabulated the results in Exhibit L. The AUSS-6 has also been the subject of clinical tests for Wound Debridment. The results of these tests are included in Exhibit L as well.

10. **Conclusions**

Based upon a review of the published literature Misonix Inc. can state that the use of an Ultrasonic Surgical Aspirator for Wound Debridement is safe and efficacious. We can also state that the AUSS-6 is substantially equivalent in this regard to the CUSA NS-100, the Misonix Inc. AUSS-5 in soft and hard tissue ablation. The AUSS-6 is also substantially equivalent to sharps debridment of wounds caused by various mechanisms such as burns, radiation and diabetes. Based upon the clinical experiences outlined herein, the Misonix Inc. AUSS-6 Ultrasonic Surgical System and Accessories pose no new issues of safety or efficacy when used for wound debridement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 - 2005

Mr. Ronald R. Manna
Vice President Regulatory Affairs
Misonix Incorporated
1938 New Highway
Farmingdale, New York 11735

Re: K050776
Trade/Device Name: AUSS-6 Ultrasonic Surgical Aspirator Systems and Accessories
Regulatory Class: Unclassified
Product Code: LFL
Dated: March 23, 2005
Received: March 28, 2005

Dear Mr. Manna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K050776**

Device Name: **AUSS-6 Ultrasonic Surgical Aspirator System and Accessories**

Indications for Use:

The Alliger AUSS-6 Ultrasonic Surgical System and Accessories are indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) tissue in the following surgical specialties:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecology
External genitalia
- condyloma
- benign tumors (lipomas, fibromas, and leiomyomas)
- malignant primary and metastatic tumors of all types and the following cystic lesions:
- Bartholin's cysts
- Vestibular adenitis
- Inclusion cysts
- Sebaceous cysts

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] General, Restorative
[illegible] Devices

K050776

510(k) Number (if known): **K050776**

Device Name: **AUSS-6 Ultrasonic Surgical Aspirator System and Accessories**

Indications for Use: (continued)

Abdominal area

any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus.

Thoracic Surgery

Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.

Wound Care

The Misonix Inc. AUSS-6 Utrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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